

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

SHIRE DEVELOPMENT LLC,	)	
SHIRE PHARMACEUTICAL	)	
DEVELOPMENT INC.,	)	
COSMO TECHNOLOGIES LIMITED, and	)	
NOGRA PHARMA LIMITED,	)	C.A. No. 10-581-KAJ
	)	
Plaintiffs,	)	
	)	
v.	)	
	)	
CADILA HEALTHCARE LIMITED (d/b/a	)	
ZYDUS CADILA) and ZYDUS	)	
PHARMACEUTICALS (USA) INC.,	)	
	)	
Defendants.	)	
	)	

**SECOND AMENDED COMPLAINT**

Plaintiffs Shire Development LLC, Shire Pharmaceutical Development Inc. (collectively, “Shire”), Cosmo Technologies Limited (“Cosmo”), and Nogra Pharma Limited (“Nogra”) (collectively, “Plaintiffs”) by their undersigned attorneys, for their Complaint against defendants Cadila Healthcare Limited, d/b/a Zydus Cadila (“Zydus Cadila”), and Zydus Pharmaceuticals (USA), Inc. (“Zydus USA”) (collectively “Defendants” or “Zydus”) herein, allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 6,773,720 (“the ’720 patent” or “the patent-in-suit”) (attached as Exhibit A).

**THE PARTIES**

2. Plaintiff Shire Development LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 725

Chesterbrook Boulevard, Wayne, Pennsylvania 19087.

3. Plaintiff Shire Pharmaceutical Development Inc. is a corporation organized and existing under the laws of the State of Maryland, having its principal place of business at 1801 Research Boulevard, Rockville, Maryland 20850.

4. Plaintiff Cosmo is a company organized and existing under the laws of Ireland, having its principal place of business at 2, Duncairn Terrace, Bray Co., Wicklow, Ireland.

5. Plaintiff Nogra is a company organized and existing under the laws of Ireland, having its principal place of business at 33 Sir John Rogerson's Quay, Dublin 2, Ireland.

6. Upon information and belief, Zydus Cadila is a company organized and existing under the laws of India, having its principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad—380015 Gujarat, India. Upon information and belief, Zydus Cadila is in the business of developing, manufacturing, and selling generic versions of prescription drugs throughout the world, including the United States and the State of Delaware.

7. Upon information and belief, Zydus USA is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 210 Carnegie Center, Suite 103, Princeton, NJ 08540. Upon information and belief, Zydus USA is engaged in the marketing and distribution of generic products manufactured by Zydus Cadila, including in the State of Delaware.

8. Upon information and belief, Zydus USA is a wholly-owned subsidiary of Zydus Cadila.

9. Upon information and belief, Zydus USA acts at the direction of, under the control of, and for the direct benefit of Zydus Cadila and is controlled and/or dominated by

Zydus Cadila. Upon information and belief, Zydus USA acts as the U.S. agent for Zydus Cadila for purposes of regulatory submissions to the U.S. Food and Drug Administration (“FDA”) seeking approval for generic drugs.

### **JURISDICTION AND VENUE**

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Zydus USA because, *inter alia*, of its continuous and systematic contacts with the State of Delaware. Upon information and belief, Zydus USA derives substantial revenue from articles used and consumed in the State of Delaware, such as the sale of Zydus USA drug products. Upon information and belief, Zydus USA maintains a website at <http://www.zydususa.com> (“the Zydus USA website”). The Zydus USA website states, “Zydus Pharmaceuticals (USA) Inc. is a globally integrated generic pharmaceutical company.” *Id.* at Company Overview. The Zydus USA website lists seventy-one Zydus USA authorized distributors, including companies with a broad distributorship network in the State of Delaware, such as Walgreens Co., Rite Aid, Wal-Mart and CVS Pharmacy. *Id.* at ADRs. For example, Walgreens Co. has at least fifty-five locations in Delaware. Upon information and belief, Walgreens offers for sale Zydus USA products, including dipyridamole tablets, paroxetine tablets, venlafaxine tablets, and ribavirin tablets.

12. Upon information and belief, Zydus USA engages in ongoing business relationships with corporations organized and existing under the laws of the State of Delaware, including Auburn Pharmaceutical, Capital Wholesale, H.D. Smith, Kerr Drug, Prescription Solutions, QK Healthcare, and SuperValu.

13. This court has personal jurisdiction over Zydus Cadila because, *inter alia*, of its continuous and systematic contacts with the State of Delaware. Upon information and

belief, Zydus Cadila markets, sells, and/or distributes pharmaceutical products throughout the United States, including in this judicial district, either directly or through one or more of its wholly-owned subsidiaries, agents, or distributors, such as Zydus USA. Zydus Cadila's annual report for 2008-09 states, "[t]he Company achieved an attractive market share . . . for the products launched in the US." Cadila Healthcare Limited, Annual Report 2009-09 at 15. In a press release, Zydus Cadila announced, "[t]he approval for Atenolol is the latest in a series of quick developments that mark Zydus Cadila's foray in the US generic market. The process which started with the setting up of Zydus Pharmaceuticals (USA) Inc. early last year, gathered momentum with filing of 12 ANDAs by the end of financial year 2003-04." Press Release, Zydus Cadila, Zydus Cadila Receives its First Approval to Market Atenolol in USA (Jan. 1, 2005).

14. Upon information and belief, separate and apart from its relationship with Zydus USA, Zydus Cadila has availed itself of the laws of the State of Delaware and engaged in a course of conduct in the State of Delaware, at least by forming a wholly-owned U.S. subsidiary, Zydus Healthcare (USA) LLC under Delaware law.

15. Upon information and belief, Zydus USA acts as an agent of Zydus Cadila. Upon information and belief, Zydus USA and Zydus Cadila operate in concert with each other and hold themselves out in the marketplace as one company. Upon information and belief, Zydus developed the generic copies of Shire's Lialda<sup>®</sup> Mesalamine Delayed Release Oral Tablets and prepared Abbreviated New Drug Application ("ANDA") No. 91-640 ("ANDA No. 91-640" or "the Zydus ANDA"), after which Zydus Cadila instructed Zydus USA to submit the ANDA as the applicant, thereby seeking approval from the FDA to market and sell the Zydus generic copies of the Shire product throughout the United States and in this judicial district.

16. Upon information and belief, by virtue of, *inter alia*, Zydus Cadila's relationship with Zydus USA in connection with the preparation and/or filing of ANDA No. 91-640, and their activities in Delaware, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of Delaware, this Court has personal jurisdiction over Zydus Cadila.

17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

### **FACTS AS TO ALL COUNTS**

18. Shire Development LLC is the owner of New Drug Application ("NDA") No. 22-000, FDA-approved for the manufacture and sale of mesalamine delayed release tablets, containing 1.2g mesalamine, which are commercialized under the name of Lialda<sup>®</sup>. Lialda<sup>®</sup> is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis.

19. Pursuant to 21 U.S.C. § 355(b)(1), the patent-in-suit is listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering Lialda<sup>®</sup>.

20. Zydus prepared and submitted ANDA No. 91-640 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic mesalamine delayed release tablets, 1.2g ("the Zydus Product").

21. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include "[a]

detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

22. Zydus sent letters addressed to Shire Development, Inc. (now Shire Development LLC) and Cosmo Technologies Limited, each dated May 27, 2010, purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding the Zydus Product ("the Zydus Notice Letters").

23. In the Zydus Notice Letters, Zydus did not allege that any claim of the '720 patent is invalid or unenforceable.

#### **FIRST COUNT**

(Infringement of the '720 Patent by Zydus USA and Zydus Cadila)

24. Shire, Cosmo, and Nogra, repeat and re-allege each of foregoing paragraphs as if fully set forth herein.

25. The '720 patent, titled "Mesalazine Controlled Release Oral Pharmaceutical Compositions," was duly and legally issued by the United States Patent and Trademark Office on August 10, 2004 to Cosmo S.p.A. on assignment from Roberto Villa, Massimo Pedrani, Mauro Ajani and Lorenzo Fossati. Cosmo S.p.A. granted Giuliani S.p.A. an exclusive license for the '720 patent. Giuliani S.p.A., in turn, granted Shire an exclusive sublicense for the '720 patent. Subsequently, Giuliani S.p.A. assigned the license agreement with Shire to Giuliani International Limited (now known as Nogra Pharma Limited) and Cosmo became the owner of the '720 patent on assignment from Cosmo S.p.A.

26. Upon information and belief, Zydus seeks FDA approval for the manufacture and/or distribution of the Zydus Product.

27. Upon information and belief, the Zydus ANDA includes a paragraph IV certification to the '720 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Zydus Product before the expiration of the '720 patent.

28. Upon information and belief, Zydus USA and/or Zydus Cadila will commercially manufacture, sell, offer for sale, and/or import the Zydus Product immediately upon FDA approval.

29. Upon information and belief, as of the date of the Zydus Notice Letters, Zydus USA and Zydus Cadila were aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

30. The submission and filing of ANDA No. 91-640 with a paragraph IV certification to the '720 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of the Zydus Product before the expiration of the '720 patent is an act of infringement by Zydus USA and/or Zydus Cadila of one or more claims of the '720 patent under 35 U.S.C. § 271(e)(2)(A).

31. Upon information and belief, the commercial manufacture, use, sale, offer for sale and/or importation into the United States of the Zydus Product that is the subject of ANDA No. 91-640 will infringe one or more claims of the '720 patent.

32. Upon information and belief, the sale or offer for sale of the Zydus Product by Zydus USA and/or Zydus Cadila would induce and/or contribute to third-party infringement of one or more claims of the '720 patent under 35 U.S.C. § 271.



33. Upon information and belief, as of the date of the Zydus Notice Letters, Zydus USA and/or Zydus Cadila were aware of the existence of the '720 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '720 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

34. The acts of infringement set forth above will cause Shire, Cosmo, and Nogra irreparable harm for which none have adequate remedy at law, unless Zydus USA and/or Zydus Cadila are preliminarily and permanently enjoined by this Court.

**SECOND COUNT**

(Induced and/or Contributory Infringement of the '720 Patent by Zydus Cadila)

35. Shire, Cosmo, and Nogra repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

36. Zydus Cadila is jointly and severally liable for Zydus USA's infringement of one or more claims of the '720 patent.

37. Upon information and belief, Zydus Cadila knowingly induced Zydus USA to infringe and/or contributed to Zydus USA's infringement of one or more claims of the '720 patent.

38. Upon information and belief, Zydus Cadila actively induced, encouraged, aided, or abetted Zydus USA's preparation and submission and filing of ANDA No. 91-640 with a paragraph IV certification to the '720 patent.

39. Zydus Cadila's inducement, encouragement, aiding, or abetting of Zydus USA's preparation, submission, and filing of ANDA 91-640 with a paragraph IV certification constitutes infringement of the '720 patent under 35 U.S.C. § 271(e)(2)(A). Further, Zydus Cadila's commercial use, sale, offer for sale and/or importation of the Zydus Product would induce and/or contribute to Zydus USA's infringement of the '720 patent under 35 U.S.C.



§ 271(b) and/or 35 U.S.C. § 271(c).

40. Upon information and belief, Zydus Cadila's inducement, encouragement, aiding, and/or abetting of the sale or offer for sale of the Zydus Proposed Product by Zydus USA would induce and/or contribute to third-party infringement of one or more claims of the '720 patent under 35 U.S.C. § 271.

41. Upon information and belief, Zydus Cadila has, continues to, and will actively induce, encourage, aid, or abet Zydus USA's infringement of the '720 patent with knowledge that it is in contravention of the rights of Shire, Cosmo, and Nogra.

42. Upon information and belief, as of the date of the Zydus Notice Letters, Zydus Cadila was aware of the existence of the '720 patent and acted without a reasonable basis for believing that it would not be liable for inducing and/or contributing to the Zydus USA infringement of the '720 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

43. The acts of infringement set forth above will cause Shire, Cosmo, and Nogra irreparable harm for which none have adequate remedy at law, unless Zydus Cadila is preliminarily and permanently enjoined by this Court.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

- (a) A judgment declaring that the '720 patent is valid and enforceable;
- (b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission and filing of ANDA No. 91-640 with a paragraph IV certification to the FDA to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 91-640 prior to the expiration of the '720 patent was an act of infringement of the '720 patent by Zydus USA and Zydus Cadila, individually and collectively;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A) and/or 35 U.S.C. § 271(a), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 91-640 prior to the expiration of the '720 patent will constitute an act of infringement of the '720 patent by Zydus USA and Zydus Cadila, individually and collectively;

(d) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), Zydus Cadila has and continues to induce and/or contribute to Zydus USA's infringement of the '720 patent based on the submission to the FDA of ANDA No. 91-640 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 91-640 prior to the expiration of the '720 patent;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Zydus Cadila would induce and/or contribute to Zydus USA's infringement of the '720 patent based on the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 91-640 prior to the expiration of the '720 patent;

(f) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the products that are the subject of ANDA No. 91-640 by Zydus USA and/or Zydus Cadila would induce and/or contribute to third-party infringement of the '720 patent;

(g) A judgment declaring that, pursuant to 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c), Zydus Cadila's inducement, encouragement, aiding, or abetting of Zydus USA's commercial manufacture, use, sale, offer for sale and/or importation in the United States

of the products that are the subject of ANDA No. 91-640 would induce and/or contribute to third-party infringement of the '720 patent;

(h) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 91-640 shall be no earlier than the date on which the '720 patent expires;

(i) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Zydus USA, Zydus Cadila, their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the products that are the subject of ANDA No. 91-640 until the expiration of the '720 patent;

(j) A judgment awarding Shire damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Zydus USA and/or Zydus Cadila commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 91-640 prior to the expiration of the '720 patent;

(k) A judgment declaring that Zydus USA and Zydus Cadila's infringement of the '720 patent based on ANDA No. 91-640 is willful if Zydus USA and/or Zydus Cadila commercially manufacture, use, sell, offer to sell and/or import any products that are the subject of ANDA No. 91-640 prior to the expiration of the '720 patent;

(l) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Shire its attorneys' fees and costs;

(m) Such other and further relief as this Court may deem just and proper.

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